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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,939	12/29/2000	Bruce L. Gibbins	01307.0003U2	9231
23859 7590 06/04/2009 Ballard Spahr Andrews & Ingersoll, LLP SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915				
EXAMINER				
GHALL, ISIS A D				
ART UNIT		PAPER NUMBER		
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06/04/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/752,939

Applicant(s)

GIBBINS ET AL.

Examiner

Isis A. Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,8,21,23-28,31-35,38-43,45-59 and 61-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,8,21,23-28,31-35,38-43,45-59 and 61-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of Final Action Filed (PTO-502)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 03/16/2009.

Claims 3, 5, 7, 9-20, 22, 29, 30, 36, 37, 44, 60 have been canceled.

Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, 61-71 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/16/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, 61-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "substantially where the catalyst is present" in claims 1 and 38 renders the claims confusing. The claims recite the catalyst mixed with the polymer matrix, i.e. diffused every where in the matrix, however, oxygen is formed only substantially, does it mean oxygen is not formed in some areas? or the catalyst is present in substantial areas only? Additionally, claims 1, 38 and 39 recite product comprising catalyst, however, it is not clear that after reaction of the catalyst with the reactant if the product will still comprises a catalyst. Does the catalyst constitute part of the final product as claimed, especially if it is only substantially used, or only present during preparation of the device and consumed to prepare oxygen? And in that case it is not present in the final product.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, 61-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murdock (US 2002/0042587) in view of Marans (US 3,511,764) and Ladin (US 5,792,090).

Applicant's claims

Claim 1 as currently presented: An oxygen-delivery matrix, comprising, a biocompatible, single unit matrix capable of delivering oxygen, comprising a)

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swellable, cross-linked polyacrylamide polymer network, b) a catalyst mixed within the cross-linked polyacrylamide polymer network, and c) oxygen in closed cells within the cross-linked polyacrylamide polymer network substantially where the catalyst is present, wherein during manufacture of the matrix, after the polyacrylamide polymer network is cross-linked, the oxygen is produced in closed cells within the cross-linked polyacrylamide polymer network by reacting the catalyst a second reactant, such that decomposition of the second reactant results in oxygen in closed cells within the cross-linked polyacrylamide network, and wherein with use of the matrix, oxygen is transferred from the closed cells.

Claim 38 as currently presented: An oxygen delivery device, comprising a biocompatible, single unit matrix capable of delivering oxygen, comprising; a) a swellable, cross-linked polyacrylamide polymer network, b) a catalyst mixed within the cross-linked polyacrylamide polymer network, c) oxygen in closed cells within the cross-linked polyacrylamide polymer network substantially where the catalyst is present, d) at least one active agent wherein the cross-linked polyacrylamide polymer network is cross-linked prior to oxygen formation, wherein the oxygen is produced by reacting the catalyst within the cross-linked polyacrylamide polymer network with a second reactant during the manufacture of the matrix to create multiple oxygen-rich closed cells within the cross-linked polyacrylamide polymer network of the matrix, wherein, with use of the matrix, oxygen is transferred from the closed cells.

Claim 39 as currently presented: A biocompatible, single unit cross-linked polyacrylamide matrix, comprising a swellable, cross-linked polyacrylamide polymer

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network, at least one active agent, a catalyst mixed within the cross-linked polyacrylamide polymer network, and oxygen in closed cells wherein the oxygen is produced within the cross-linked polyacrylamide polymer network by the reaction of the catalyst and a second reactant, wherein the polyacrylamide polymer network is cross-linked prior to gas formation.

Therefore, the present claims 1, 38 and 39 recite a product comprises matrix of closed cell foam of cross-linked polyacrylamide polymer containing oxygen produced during the manufacture of the product by reaction of catalyst and reactant. The limitation of how oxygen is produced and when polyacrylamide is crosslinked are directed to process of making the product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695,698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Determining the scope and contents of the prior art (MPEP§ 2141.01)

Murdock teaches polymeric cross-linked foam reservoir comprising cellulose derivatives and active agent including anti-infective agents and growth factors (abstract; paragraphs 0035, 0049, 0050). The foam reservoir is closed cell foam wherein the closed cells can be produced chemically and contains gasses including oxygen (paragraph 0036).

Marans teaches cross-linked polyacrylamide foam foamed by decomposition product of another polymer during manufacture of the polymer to provide uniform closed cell foam matrix that swells and absorbs water but not dissolve. Foaming of polyacrylamide was performed during the manufacture of the polyacrylamide crosslinked polymer (See the entire document, and especially col.1, lines 12-16, 20-26; col.2, lines 54-59; col.4, lines 6-8).

Ladin teaches wound dressing that supply oxygen to the wound for optimal healing and minimization of infection because the wound causes diffusion limited access and limits the oxygen supply to the wound (abstract; col.2, lines 28-31). The dressing comprises polymeric foam comprising elements that react to generate oxygen that are hydrogen peroxide and catalyst such as magnesium dioxide or enzymes (col.6, lines 6-26). The catalyst is contained in the foam which absorbs hydrogen peroxide into the foam to produce oxygen (col.7, lines 48-55). The foam comprises guar gum or polyacrylamide, and further comprises collagen, i.e. non-gellable foam (col.4, lines 39-42; col.12, line 7).

**Ascertaining the differences between the prior art and the claims at issue,
and resolving the level of ordinary skill in the pertinent art (MPEP § 2141.012)**

Although Murdock teaches water swellable closed cell cross-linked polymer foam reservoir, however, Murdock does not explicitly teach polyacrylamide polymer as claimed in claims 1, 38 and 39. Although Murdock teaches closed cell foam containing gas that can be produced chemically, however, the reference does not explicitly teach

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the specific chemical reaction that produces the gas in the foam as claimed in claims 1, 38 and 39.

Therefore, at the time of the invention it was known to treat wound using closed cell crosslinked polymeric foam containing oxygen that is produced chemically in the foam as taught by Murdock. Cross-linked polyacrylamide closed cell foam was known at the time of the invention to absorb water without dissolving, and it was further known to form uniform crosslinked polyacrylamide foam when foaming is performed during the manufacture of the crosslinked polyacrylamide polymer as taught by Marans.

Additionally, forming oxygen in a foam matrix by chemical reaction between peroxide and catalyst was known at the time of the invention as taught by Ladin. Furthermore, Ladin taught the benefit of oxygen for the wound.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide polymeric cross-linked closed cell foam wound dressing containing oxygen that can be produced chemically as disclosed by Murdock, and replace the closed cell cross-linked polymer foam with crosslinked polyacrylamide closed cell foam that taught by Marans. One would have been motivated to do so because Marans teaches that cross-linked polyacrylamide closed cell foam can absorb water without dissolving and one would have been motivated to form the bubbles in the crosslinked polymer during the manufacture of the crosslinked polymer because Marans teaches that such process provides a uniform foam. One would have reasonably expected formulating cross-linked polyacrylamide closed cell foam containing oxygen that can be produced chemically wherein the foam is uniform and absorbs water without

dissolving. Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to produce the crosslinked polyacrylamide closed cell foam containing oxygen in the bubbles as disclosed by the combination of Murdock and Marans, and further produce the oxygen during the formation of the foam by the reaction of hydrogen peroxide and catalyst as disclosed by Ladin. One would have been motivated to do so because Ladin teaches that foam containing oxygen are optimal for wound healing and minimizing infection. One would reasonably expected formulating cross-linked polyacrylamide closed cell foam containing oxygen that is produced chemically by the reaction of peroxide and catalyst wherein the foam is uniform and absorbs water and further has optimal wound healing effect with minimal infection.

Resolving the level of ordinary skill in the pertinent art (MPEP § 2141.012)

One skilled in the art at the time of the invention would be motivated to prepare wound dressing of closed cell foam of crosslinked polyacrylamide containing oxygen in the bubbles of the foam, wherein the dressing absorb water and deliver oxygen to the wound to optimize its healing and minimize its infection.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. In re Bozek, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a) because the invention as a whole is taught by the combined teaching of the cited references.

Response to Arguments

8. Applicant's arguments filed 03/16/2009 have been fully considered but they are not persuasive.

Applicants' arguments are moot in view of the new ground of rejection. However, the examiner is hereby responding to the argument against Murdock (US '587) and Ladin (US '090) since they are included in the new current rejection.

Applicants argue that US '587 does not teach foaming cross-linked polymeric network wherein the gas is introduced to the polymer prior to crosslinking and teaches formation of foam by stirring a polymer solution with high speed or by gas injection. Therefore, the gas is introduced into the composition when the polymer solution is a liquid and before the polymer solution is cross-linked.

In response to this argument, applicants' attention is drawn to the scope of the present claims that is directed to a product comprising cross-linked matrix containing oxygen in closed cells. US '587 teaches polymeric cross-linked foam reservoir comprising cross-linked polymer and closed cell containing oxygen that can be produced chemically. US '587 suggests chemical formation of gas in the closed cells.

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Regarding product by process claims, it has been held that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695,698, 227 USPQ 964, 966 (Fed. Cir. 1985). Cross linking of the polymer matrix before or after addition of oxygen does not impart patentability to the claims because it has been held that it is prima facie obvious to reverse the order of the prior art process steps, *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690,69 USPQ 330 (CCPA 1946), selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results; *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930), selection of any order of mixing ingredients is prima facie obvious. Applicants failed to show superior and unexpected results obtained from cross-linking before forming oxygen or after forming oxygen in the matrix. Additionally, regarding the order of steps, it is argued that US '587 teaches product comprising oxygen within the cross-linked matrix, and US '090 teaches the use of cross-linked polyacrylamide and the chemical reaction that produces the oxygen, therefore, the combination of the references would teach cross-linked polyacrylamide matrix comprising closed cells containing oxygen. The invention as a whole is taught by the combination of the references.

Applicants further argue that there is no suggestion or motivation to make the proposed modification of the polyacrylamide of the US '090 in the foam of US '587, and replacement of the polymer of US '587 with polyacrylamide of the '090 would altered the entire teachings of US '587 and renders the matrix of US '587 unsatisfactory to its intended purpose and a gelatinous mass may result and polyacrylamide would not cross-link.

In response to this argument, it is argue that US '090 teaches method for chemical generation of oxygen using catalyst and peroxide that is suitable for wound dressings and also teaches polyacrylamide matrix containing the oxygen. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to replace cross-linked polymer with polyacrylamide and generate oxygen into the wound dressing disclosed by US '587 using catalyst and peroxide as used by US '090 because US '090 teaches polyacrylamide matrix comprising oxygen reduced infection, with reasonable expectation of having cross-linked polyacrylamide matrix containing closed cell foam entrapping oxygen produced chemically by the reaction of hydrogen peroxide and catalyst with minimal infection to the underlying skin. The invention as a whole is taught by the combination of US '587 and US '090. An article comprising cross-linked polyacrylamide matrix and oxygen in closed cells as claimed would have been obvious to one skilled in the art at the time the invention was made because the prior art recognized cross-linked polymeric matrix containing oxygen in closed cell delivered chemically and also recognized the suitability of polyacrylamide and the oxygen generation from reaction off catalyst and peroxide in wound dressing. It

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has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

Applicants argue that US '587 does not teach transfer of oxygen from the matrix and its delivery.

In response to this argument that, it is argued that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. US '587 is directed to wound treatment as intended by the present invention.

Applicants argue that US '090 does not cure the deficiencies of US '587 as it teaches occlusive dressing not capable for delivering oxygen, and teaches reservoir or sponge or open cell foam. The combination of the references would not result into the present invention.

In response to this argument, it is argued that US '090 is relied upon for the solely teaching of catalyst/peroxide reaction to produce oxygen in a wound dressing matrix made of polyacrylamide. The cross-linked polymer matrix is taught by US '587, but US '587 does not specifically teach polyacrylamide. In view of the newly presented rejection, crosslinked polyacrylamide was known at the time of the invention. Further, US '090 teaches advantage of dressing comprising polyacrylamide polymer and oxygen generated from the reaction of catalyst and peroxide to supply oxygen to the wound for optimal healing and minimization of infection, and this would have been motivated one having ordinary skill in the art at the time of the invention to replace the polymer matrix disclosed by US '587 with polyacrylamide matrix and create oxygen by the reaction of catalyst and peroxide as disclosed by US '090. The present language of the claims does not exclude the presence of occlusive layer, and US '090 teaches delivery of oxygen and does not teach that the occlusive layer to prevent the oxygen delivery, but to prevent escape of oxygen from the device to the atmosphere.

Claim Objections

9. Claim 1 is objected to because of the following informalities: claim 1 has a period in the middle of the claim in line 8 following the word "cross-linked", and the claims should have only one period at the end. Appropriate correction is required.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-

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0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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